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Aug. 14, 2006 — Date Charles P. Landrum

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
McBride *et al.*

Serial No.: 10/701,038

Filed: November 4, 2003

For: P153 AND P156 ANTIGENS FOR THE IMMUNODIAGNOSIS OF CANINE AND HUMAN EHRLICHIOSES AND USES THEREOF

Group Art Unit: 1645

Examiner: Zeman, R.

Atty. Dkt. No.: CLFR:235US

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

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APPEAL BRIEF

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MS Appeal Brief - Patents
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Sir:

Appellants hereby submit this Appeal Brief to the Board of Patent Appeals and Interferences in response to the Office Action dated January 9, 2006. The Notice of Appeal was received by the Patent Office on May 12, 2006, as indicated by a stamped return postcard. Appellants request a one month extension of the July 12, 2006 deadline to file an Appeal Brief up to and including August 14, 2006, being that August 12, 2006 falls on a Saturday. The one-month extension fee of $60.00 is enclosed.

The fee for filing this Appeal Brief is $250.00 and is included herewith.

It is believed that no additional fees are due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski Deposit Account No. 50-1212/CLFR:235US.

Please date stamp and return the attached postcard as evidence of receipt.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Research Development Foundation, Carson City, Nevada.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF THE CLAIMS

Claims 1-26 were originally filed. In the Response filed January 18, 2005 to the Restriction Requirement dated December 15, 2004 Applicants elected Group II, Claims 6 and 15, and elected to pursue SEQ ID NO: 2, withdrawing claims 1-5, 7-14, and 16-26 from consideration. In the Response filed on September 19, 2005 to the Office action dated April 25, 2005, which was supplemented with the Response of October 17, 2005 to Notice of Non-Compliant Amendment dated September 30, 2005, claim 6 was amended and new claims 27-34 were added. The Office action dated January 9, 2006 maintained the rejection of claims 6, 15 and 27-34 as lacking written description. Thus, claims 6, 15 and 27-34 are currently pending, stand rejected, and are appealed. (see VIII. Claims Appendix).

IV. STATUS OF AMENDMENTS

The final Office Action mailed January 9, 2006 acknowledges the amendments included in the Response to Notice of Non-Compliant Amendment of October 17, 2005 and in the Response to final Office Action of September 19, 2005. The Response of September 19, 2005 included amendment of claim 6 and the addition of claims 27-34. Applicants' Response on

March 9, 2006 to final Office Action mailed January 9, 2006 contained claim amendments addressing all issues outstanding in the final Office Action mailed January 9, 2006. The Advisory Action mailed March 31, 2006, denied entry of the March 9, 2006 amendments filed with the Response to Final Office action filed March 9, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The principal claim, claim 6, is directed to an isolated and purified polypeptide of *Ehrlichia canis* immunoreactive surface protein p153 encoded for by DNA selected from the group consisting of (a) isolated DNA which encodes a p153 protein having the amino acid sequence shown in SEQ ID NO: 2; (b) isolated DNA differing from the isolated DNA of (a) in codon sequence due to the degeneracy of the genetic code; (c) isolated DNA sequence comprising nucleotides 1080 to 1990 of *Ehrlichia canis* immunoreactive surface protein p153 gene; (d) isolated DNA sequence comprising nucleotides 1950 to 2950 of *Ehrlichia canis* immunoreactive surface protein p153 gene; and (e) isolated DNA sequence comprising nucleotides 2940 to 4220 of *Ehrlichia canis* immunoreactive surface protein p153 gene. Support for this embodiment of the invention is found, at least on page 10, lines 1-10 and page 15, lines 12-18 of the specification.

Dependent claim 15 is directed to a composition comprising an isolated and purified polypeptide of *Ehrlichia canis* immunoreactive surface protein p153 as defined in claim 6. Support for this embodiment of the invention is found, at least on page 16, lines 5-7 of the specification.

Dependent claim 27 is directed to a polypeptide described in claim 6 that is immobilized on a surface. Support for this embodiment of the invention is found, at least on page 16, line 17 to page 17, line 3 of the specification.

Dependent claim 28 is directed to a polypeptide of claim 27 wherein the surface is a membrane. Support for this embodiment of the invention is found, at least on page 16, line 17 to page 17, line 3 of the specification.

Dependent claim 29 is directed to a polypeptide of claim 27 wherein the surface is a microtiter plate. Support for this embodiment of the invention is found, at least on page 16, line 17 to page 17, line 3 of the specification.

Dependent claim 30 is directed to a polypeptide of claim 6 wherein the polypeptide is an *Ehrlichia canis* immunoreactive surface protein p153 polypeptide. Support for this embodiment of the invention is found, at least on page 12 to page 14 of the specification.

Dependent claim 31 is directed to a composition comprising the peptide of claim 30. Support for this embodiment of the invention is found, at least on page 16, lines 5-7 of the specification.

Dependent claim 32 is directed to the polypeptide of claim 30 immobilized on a surface. Support for this embodiment of the invention is found, at least on page 16, line 17 to page 17, line 3 of the specification.

Dependent claim 33 is directed to the polypeptide of claim 32 wherein the surface is a membrane. Support for this embodiment of the invention is found, at least on page 16, line 17 to page 17, line 3 of the specification.

Dependent claim 34 is directed to the polypeptide of claim 32 wherein the surface is a microtiter plate. Support for this embodiment of the invention is found, at least on page 16, line 17 to page 17, line 3 of the specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues addressed in this Appeal include:

(a) Whether the written description for the sequence of an *Ehrlichia canis* immunoreactive surface protein p153 gene is sufficient under 35 U.S.C. §112, first paragraph;

(b) Whether claims 6, 15, and 27-34 are definite relative to the sequence for *Ehrlichia canis* p153 gene;

(c) Whether the subject matter of claim 30 directed to a full length p153 polypeptide, further limits claim 6 directed to segments of p153; and

(d) Whether sufficient antecedent basis is present for the term "surface" in claims 33 and 34.

VII. ARGUMENT

A. Rejections under 35 U.S.C. §112

1. Claims 6, 15, and 27-34 Satisfy the Written Description Requirement of 35 U.S.C. §112, first paragraph

Claims 6, 15, and 27-34 are rejected as failing to comply with the written description requirement because the claims allegedly contain subject matter not described in the specification in such way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The

Action alleges that no baseline sequence is provided for the *E. Canis* immunoreactive surface protein p153 gene and none of the claimed proteins meet the written description requirement. The Action cites *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601, and *Amgen, Inc. v Chugai Pharmaceutical,* 927 F.2d 1200, 18 USPQ2d 1016, in support of the rejection. Applicants disagree.

Applicants have addressed the Examiner's concerns in their response to final Office Action by submitting amended claims containing reference to GenBank accession number AF252298. However, the Examiner denied entry of these claims. Nonetheless, the presently pending claims satisfy the written description requirement.

First, It is Applicants' position that the Examiner has failed to make out a prima facie case of lack of written description. As stated in the MPEP 2163(II)(A):

> The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96 [] The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis....

The MPEP also provides that an Examiner should review the entire application to understand how applicant provides support for the claimed invention. MPEP 2163(II)(A)(2) states:

> Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention....

The present specification clearly sets forth the sequences of *Ehrlichia canis* immunoreactive surface protein p153 polypeptide and gene as provided in GenBank accession number AF252298. The Examiner's statement that "no baseline sequence is provided for [] the *Ehrlichia canis* immunoreactive surface protein p153 gene," does not establish a prima facie lack of written description, particularly in light of GenBank accession number AF252298. None of the reasons set forth in the final Office Action establish any fact that would shift the burden of establishing adequate written description to the Applicants. The Examiner has failed to provide evidence or reason why the claims read in light of the specification lack written description.

Second, Applicants provide written description for an *Ehrlichia canis* immunoreactive surface protein p153 polypeptide and gene in the specification as GenBank accession number AF252298. The specification on Page 14, line 9 to line 14 discloses the revised sequence for the *E. canis* p153 gene and polypeptide as GenBank accession number AY156950. However, the AF252298 record was updated to include the revised sequence instead of establishing the new accession number. The current AF252298 record (Exhibit 1) states that the revised sequence (a) was submitted on September 30, 2002 and (b) replaced the earlier version of accession number AF252298 (gi:12658962; Exhibit 2). Exhibit 1 is a copy of the current GenBank entry for accession number AF252298 and Exhibit 2 is a copy of GenBank entry prior to replacement with the full length p153 sequence, each of which were made of record in Applicants' Response dated September 19, 2005. Thus, GenBank accession number AF252298 provides a baseline sequence for amino acid and nucleic acid sequences of the *E. canis* immunoreactive surface protein p153 protein and gene, respectively. One of skill in the art, based on disclosure of the nucleic acid and amino acid sequence of the *E. canis* immunoreactive surface protein p153, *i.e.*, GenBank accession number AF252298, had access to the sequences of the *E. canis* immunoreactive

surface protein p153 and would have reasonably concluded that Applicants possessed the subject matter claimed as of the priority date of the present application, November 4, 2002.

In addition, the present invention is distinct from the facts underlying the *Fiers v. Revel* and *Amgen v Chugai* cases, which were cited in support of the rejection. In these cases the conception date of a nucleic acid sequence was the date the actual DNA sequence was know and the holdings are that the description of methods for isolating a fragment of DNA and methods for isolating a corresponding mRNA is insufficient description of a nucleic acid sequence or an amino acid sequence encoded by the nucleic acid. In contrast, in the present case the DNA sequence was know and submitted to GenBank prior to the priority date of the present application. The present application does not rely on methods of isolation for identifying or describing the nucleic acid or polypeptide sequences, it discloses the sequences in the application by reference to the GenBank accession number. Therefore, the present application provides more than the mere description of the methods for isolating a DNA sequence. Thus, the holdings in *Fiers v. Revel* and *Amgen v Chugai* are not relevant to the present application. Applicants were in possession of the invention and the GenBank accession number describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Applicants note that none of the rejections speak to the insufficiency of GenBank accession number AF252298 and no notification of informalities regarding the sequence listing was conveyed to the Applicants during prosecution.

2. Claims 6, 15, and 27-34 are Definite and Satisfy the Requirements of 35 U.S.C. §112, second paragraph

Claims 6, 15, and 27-34 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as their invention. The claims are allegedly vague and indefinite for the following reasons: (a) claim 6 for not referencing a baseline sequence, and (b) claim 33 and 34 for lacking antecedent basis for "surface."

a) Claim 6, 15, 27-34 are Definite

The Examiner alleges that no baseline sequence is provided for the claimed gene. Applicants addressed this issue by providing in the amendment after final Office Action reference to GenBank accession number AF252298. The amendment was not entered by the Examiner. Nonetheless, as discussed above and incorporated here by reference, one of skill in the art reading the claims in light of the specification would have readily recognized the baseline sequence of the *E. canis* immunoreactive surface protein p153 is GenBank accession number AF252298. The pending claims satisfy 35 U.S.C. §112, second paragraph.

b) Claims 33 and 34

The Examiner indicates that claims 33 and 34 lack antecedent basis for the term "surface." Again, Applicants addressed this rejection in amendments not entered by the Examiner. However, this insufficiency is easily addressed by clarification of claim dependency and Applicants can address upon remand to the Examiner.

B. Objections under 37 C.F.R. §1.175

1. Claim 30 Further Limits the Subject Matter of Claim 6

Claim 30 is objected to as failing to further limit the subject matter of a previous claim. Applicants respectfully disagree.

Claim 30 does further limit the subject matter of claim 6. Claim 6 is directed to segments of the *E. canis* p153 protein and reads in part "...isolated DNA which encodes a p153 protein having the amino acid sequence shown in SEQ ID NO: 2." SEQ ID NO:2 represents a segment of the P153 protein. Claim 30 is directed to the full length *E. canis* protein and reads "The isolated and purified polypeptide of claim 6, wherein the polypeptide is an *Ehrlichia canis* immunoreactive surface protein p153 polypeptide." The full length *E. canis* p153 protein is described in the specification on page 14 that reads:

> Anti-p43 antibody reacted with a native protein of approximately 200 kD in *E. canis* whole cell lysates. Furthermore, this 200 kD protein was also recognized by sera from an *E. canis* infected dog (Figure 5). A partial gene sequence previously identified as p43 (N-terminal portion of the p153) assigned GenBank accession number AF252298. The amended sequencing encoding p153 was assigned the GenBank accession number AY156950.

GenBank accession number AF252298 was amended to encompass the sequence of GenBank accession number AY15690, see above for a more detailed discussion. GenBank accession AF252298 describes the full length *E. canis* p153 polypeptide. The polypeptide segments of claim 6, in particular the segment having the amino acid sequence of SEQ ID NO:2, are not equivalent to the *Ehrlichia canis* immunoreactive surface protein p153 polypeptide of claim 30. Thus, claim 30 is distinct from and further limits the claim 6 to the full length polypeptide sequence.

2. Claims 31, 32, 33, and 34 are Distinct from Claims 15, 27, 28, and 29

Claims 31, 32, 33 and 34 are objected to as being substantial duplicates of claims 15, 27, 28, and 29. This objection is related to the previously argued objection related to the alleged failure to further limit the subject matter of a previous claim. The arguments set forth above relating to the objection of claim 30 are incorporated here by reference. Since claim 30 is distinct from claim 6, claims 31, 32, 33, and 34, which depend from claim 30, are distinct from claims 15, 27, 28, and 29, which depend from claim 6.

C. Grouping of Claims

The evidence of record overwhelmingly indicates that the present invention satisfied the requirements under 35 U.S.C. §112. In particular, that GenBank accession AF252298 describes the amino acid and nucleic acid sequence of the *E. Canis* immunoreactive surface protein p153 and provides a basis for nucleic acid and amino acid sequences presently claimed. The claims stand or fall together.

D. Conclusion

For the above-argued reasons, Appellants respectfully request that the rejection of claims 6, 15, and 27-34 be reversed. Appellants have provided arguments that overcome the pending rejections. Appellants respectfully submit that the Examiner's conclusion that the claims should be rejected is unwarranted. It is therefore again requested that the Board overturn the Examiner's rejection.

Please date stamp and return the enclosed postcard to evidence receipt of this document.

Respectfully submitted,

Charles P. Landrum
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Agent for Appellants

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Date: August 14, 2006

VIII. CLAIMS APPENDIX

1. (Withdrawn) DNA encoding an *Ehrlichia canis* immunoreactive surface protein p153, said DNA is selected from the group consisting of:

   (a) isolated DNA which encodes a p153 protein having the amino acid sequence of SEQ ID NO: 2; and

   (b) isolated DNA encoding said protein, wherein the sequence of said DNA differs from the isolated DNA of (a) in codon sequence due to the degeneracy of the genetic code.

2. (Withdrawn) A vector comprising the DNA of claim 1 and regulatory elements necessary for expression of the DNA in a cell.

3. (Withdrawn) The vector of claim 2, wherein said DNA encodes a p153 protein having the amino acid sequence shown in SEQ ID NO: 2.

4. (Withdrawn) A host cell transfected with the vector of claim 2, said vector encodes a p153 protein having the amino acid sequence shown in SEQ ID NO: 2.

5. (Withdrawn) The host cell of claim 4, wherein said cell is selected from group consisting of bacterial cells, mammalian cells, plant cells and insect cells.

6. (Previously presented) An isolated and purified polypeptide of *Ehrlichia canis* immunoreactive surface protein p153 encoded for by DNA selected from the group consisting of:

(a) isolated DNA which encodes a p153 protein having the amino acid sequence shown in SEQ ID NO: 2;

(b) isolated DNA differing from the isolated DNA of (a) in codon sequence due to the degeneracy of the genetic code;

(c) isolated DNA sequence comprising nucleotides 1080 to 1990 of Ehrlichia canis immunoreactive surface protein p153 gene;

(d) isolated DNA sequence comprising nucleotides 1950 to 2950 of Ehrlichia canis immunoreactive surface protein p153 gene; and

(e) isolated DNA sequence comprising nucleotides 2940 to 4220 of Ehrlichia canis immunoreactive surface protein p153 gene.

7. (Withdrawn) DNA encoding an *Ehrlichia chaffeensis* immunoreactive surface protein p156, said DNA is selected from the group consisting of:

(a) isolated DNA which encodes a p156 protein having the amino acid sequence of SEQ ID NO: 1; and

(b) isolated DNA encoding said protein, wherein the sequence of said DNA differs from the isolated DNA of (a) in codon sequence due to the degeneracy of the genetic code.

8. (Withdrawn) A vector comprising the DNA of claim 7 and regulatory elements necessary for expression of the DNA in a cell.

9. (Withdrawn) The vector of claim 8, wherein said DNA encodes a p156 protein having the amino acid sequence shown in SEQ ID NO: 1.

10. (Withdrawn) A host cell transfected with the vector of claim 8, said vector encodes a p156 protein having the amino acid sequence shown in SEQ ID NO: 1.

11. (Withdrawn) The host cell of claim 10, wherein said cell is selected from group consisting of bacterial cells, mammalian cells, plant cells and insect cells.

12. (Withdrawn) Isolated and purified *Ehrlichia chaffeensis* immunoreactive surface protein p156 encoded for by DNA selected from the group consisting of:

(a) isolated DNA which encodes a p156 protein having the amino acid sequence shown in SEQ ID NO: 1; and

(b) isolated DNA differing from the isolated DNA of (a) in codon sequence due to the degeneracy of the genetic code.

13. (Withdrawn) An antibody directed against the p153 protein of claim 6.

14. (Withdrawn) An antibody directed against the p156 protein of claim 12.

15. (Previously presented) A composition comprising a p153 polypeptide of claim 6.

16. (Withdrawn) A vaccine against canine ehrlichiosis comprising the p156 protein of claim 12.

17. (Withdrawn) A method of determining whether a dog is infected with an *Ehrlichia* species, comprising the step of: determining whether serum from said dog reacts with *E. canis* p153 protein or *E. chaffeensis* p 156 protein, wherein reaction with the p153 protein or the p156 protein indicates said dog is infected with *Ehrlichia canis* and *Ehrlichia chaffeensis*, respectively.

18. (Withdrawn) The method of claim 17, wherein said protein is a recombinant protein.

19. (Withdrawn) The method of claim 17, wherein western blot analysis is used to determine whether the serum of said dog reacts with said protein.

20. (Withdrawn) The method of claim 17, further comprising the step of determining whether the serum from said dog reacts with *E. canis* p28 protein, wherein

immunoreactivity to both the p153 and p28 proteins indicates said dog is infected with *Ehrlichia canis*.

21. (Withdrawn) A serodiagnostic kit for determining whether a dog is infected with an *Ehrlichia* species, said kit comprising: a) one or more immobilized Ehrlichia antigens selected from the group consisting of p153, p43, p156 and p28; b) appropriate dilution buffers for dog serum; c) an anti-dog serum second antibody linked to a reporter molecule; and, d) appropriate reagents for detection of said reporter molecule.

22. (Withdrawn) The kit of claim 21 wherein said Ehrlichia antigens are immobilized on a membrane or a microtiter plate.

23. (Withdrawn) The kit of claim 21, wherein said reporter molecule is selected from the group consisting of luciferase, horseradish peroxidase, β-galactosidase, and fluorescent labels.

24. (Withdrawn) A method of determining whether a dog has been infected with an *Ehrlichia* species, comprising the steps of: extracting DNA from the blood of said dog; and performing PCR amplification on said DNA with oligonucleotide primers specific for the *E. canis* p153 gene or the *E. chaffeensis* p156 gene; separating the resulting PCR product by size, wherein positive detection of an appropriately sized amplification product indicates infection with *E. canis* or *E. chaffeensis*.

25. (Withdrawn) The method of claim 24, wherein said PCR product is detected by gel electrophoresis.

26. (Withdrawn) A kit for determining whether a dog is infected with an *Ehrlichia* species, said kit comprising: a) reagents for DNA extraction from blood; b) p153-specific or p156-specific oligonucleotides; reagents for DNA extraction from blood; and, c) reagents for PCR amplification.

27. (Previously Presented) The isolated and purified polypeptide of claim 6, wherein the protein is immobilized on a surface.

28. (Previously Presented) The isolated and purified polypeptide of claim 27, wherein the surface is a membrane.

29. (Previously Presented) The isolated and purified polypeptide of claim 27, wherein the surface is a microtiter plate.

30. (Previously Presented) The isolated and purified polypeptide of claim 6, wherein the polypeptide is an *Ehrlichia canis* immunoreactive surface protein p153 polypeptide.

31. (Previously Presented) A composition comprising a p153 polypeptide of claim 30.

32. (Previously Presented) The isolated and purified polypeptide of claim 30, wherein the protein is immobilized on a surface.

33. (Previously Presented) The isolated and purified polypeptide of claim 30, wherein the surface is a membrane.

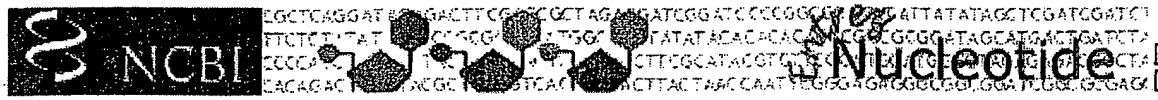
34. (Previously Presented) The isolated and purified polypeptide of claim 30, wherein the surface is a microtiter plate.

IX. EVIDENCE APPENDIX

Exhibit 1 – Copy of GenBank accession number AF252298 (gi:37528969), made of record in Applicants Response dated September 19, 2005 to the non-final Office Action mailed April 25, 2005 as Exhibit 2.

Exhibit 2 – Copy of GenBank accession number AF252298 (gi:12658962), made of record in Applicants Response dated September 19, 2005 to the non-final Office Action mailed April 25, 2005 as Exhibit 1.

EXHIBIT 1



☐ 1: AF252298. Reports Ehrlichia canis 2...[gi:37528969] Links

Comment Features Sequence

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  TITLE     Immunodiagnosis of Ehrlichia canis infection with recombinant
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  JOURNAL   J. Clin. Microbiol. 39 (1), 315-322 (2001)
   PUBMED   11136790
REFERENCE   2  (bases 1 to 4266)
  AUTHORS   McBride,J.W., Comer,J.E. and Walker,D.H.
  TITLE     Novel Immunoreactive Glycoprotein Orthologs of Ehrlichia spp
  JOURNAL   Ann. N. Y. Acad. Sci. (2003) In press
REFERENCE   3  (bases 1 to 4266)
  AUTHORS   McBride,J.W. and Walker,D.H.
  TITLE     Direct Submission
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EXHIBIT 2

1: AF252298. Reports ...[gi:12658962] The record has been replaced by 37528969

Comment Features Sequence

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DEFINITION  Ehrlichia canis 43 kDa surface protein gene, complete cds.
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KEYWORDS    .
SOURCE      Ehrlichia canis
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REFERENCE   1  (bases 1 to 1173)
  AUTHORS   McBride,J.W., Corstvet,R.E., Breitschwerdt,E.B. and Walker,D.H.
  TITLE     Immunodiagnosis of Ehrlichia canis infection with recombinant
            proteins
  JOURNAL   J. Clin. Microbiol. 39 (1), 315-322 (2001)
   PUBMED   11136790
REFERENCE   2  (bases 1 to 1173)
  AUTHORS   McBride,J.W. and Walker,D.H.
  TITLE     Direct Submission
  JOURNAL   Submitted (04-APR-2000) Pathology, University of Texas Medical
            Branch, 301 University Blvd., Galveston, TX 77555, USA
COMMENT     [WARNING] On Oct 6, 2003 this sequence was replaced by a newer
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X. RELATED PROCEEDINGS APPENDIX

NONE.